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MAILED

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OFFICE OF PETITIONS

In re Patent No. 7,498,349 :
Burli et al. :
Issue Date: March 3, 2009 :
Application No. 10/523,422 : DECISION ON REQUEST FOR
Filed: October 6, 2005 : RECONSIDERATION OF
Attorney Docket No. 020891- : PATENT TERM ADJUSTMENT
001411US :
Title: Biaryl Compounds Having :
Anti-Infective Activity :

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)," filed May 1, 2009.

The application for reconsideration of patent term adjustment is **DISMISSED**.

The above-identified application matured into U.S. Patent No. 7,498,349 on March 3, 2009. The patent issued with a patent term adjustment of 344 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See, 37 CFR 1.705(d). Patentees request that the patent term adjustment determination for the above-identified patent be changed from 344 days to 492 days.

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under 35 U.S.C. 154(b)(1)(A) overlaps with a delay under 35 U.S.C. 154(b)(1)(B) only if the delays occur on the same day.

The petition submitted by patentee sets forth a period of adjustment for Office delays totaling 148 days (Three Year Delay

under 37 CFR 1.703(b) plus a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a) of 404 days). The petition also reflects a reduction of patent term adjustment totaling 60 days for applicants' failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. Thus, patentee asserts entitlement to an overall adjustment of 492 days ($404+148=552$ days for Office delays less 60 days for applicants' delay).

Patentees' petition does not dispute the adjustments under 37 CFR 1.702(a) totaling 404 days. Patentee's petition acknowledges the reductions for applicants' failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. These reductions total 60 days.

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704.

The Office agrees that because certain actions were not taken within specified time frames, the patent is entitled to an adjustment of 404 days pursuant to 37 CFR 1.702(a). It should be noted that the calculation of any over three year delay for a application filed pursuant to 35 USC 371 is calculated based upon the commencement date. In this instance the commencement date of the application is February 2, 2005. Thus, the application was pending three years and 395 days until the issuance of the patent on March 3, 2009.

At issue is whether patentees should accrue an additional 395 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 404 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 395 days overlap. Patentee's calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of

any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing or commencement date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing or commencement date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See, 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See, Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See, also, Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See, also, Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing or commencement date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154(b)(1)] are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the

actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing or commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application commenced, February 2, 2005, to the date the patent issued on March 3, 2009. Prior to the issuance of the patent, 344 days of patent term adjustment were accorded for the Office failing to respond within specified time frames during the pendency of the application. The 404 days accorded pursuant to 37 CFR 1.702(a) overlap with the 395 days of Office delay under 37 CFR 1.702(b).

The application actually issued three years and 148 days after its filing date. The Office did not delay 404 days and then delay an additional 395 days. Accordingly, 344 days of patent term adjustment (not 404 days and 148 days) was properly entered because the period of delay of 395 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 404 days attributable to grounds specified in § 1.702(a). Entry of both periods is not warranted. Thus, 404 days, which includes the 395 days pursuant to 37 CFR 1.702(a), is determined to be the actual number of days that the issuance of the patent was delayed by the Office.

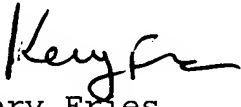
Accordingly, at issuance, the Office properly entered an overall adjustment of 344 days of patent term adjustment for the Office taking in excess of three years to issue the patent.

¹ The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

In view thereof, no adjustment to the patent term will be made because the correct adjustment of 344 days is properly set forth in the Letters Patent (adjustments totalling 404 days less reductions totalling 60 days).

The Office acknowledges submission of the required \$200.00 application fee. See, 37 CFR 1.18(e).

Telephone inquiries specific to this matter should be directed to Petitions Attorney Charlema Grant, at (571) 272-3215.

A handwritten signature in black ink, appearing to read "Kery Fries", with a stylized flourish at the end.

Kery Fries
Senior Legal Advisor Attorney
Office of Patent Legal Administration

I hereby certify that this correspondence is being filed via
EFS-Web with the United States Patent and Trademark Office
on May 1, 2009

PATENT
Docket No.: 020891-001411US

TOWNSEND and TOWNSEND and CREW LLP

By: 
Lukas K. Szymanski

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Roland W. BURLI

Patent No.: 7,498,349

Issued: March 3, 2009

Application No.: 10/523,422

Filed: October 6, 2005

For: Biaryl Compounds Having Anti-
Infective Activity

Customer No.: 20350

Confirmation No.: 1167

Examiner: Nolan, Jason Michael

Art Unit: 1626

**REQUEST FOR
RECONSIDERATION OF PATENT
TERM ADJUSTMENT
DETERMINATION
UNDER 37 C.F.R. § 1.705(d)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to 37 C.F.R. § 1.705(d), Applicants respectfully request reconsideration of the patent term adjustment determination. This request is accompanied by the fee set forth in §1.18(e) and a statement of facts as required under 37 C.F.R. § 1.705(b)(2).

In view of the following it is respectfully requested that Applicants be granted a corrected patent term adjustment of 492 days.

Statement of Facts as required under 37 C.F.R. § 1.705(b)(2)

The correct patent term adjustment is 492 days, not 344 days as stated on the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) mailed on September 17, 2008 with the Notice of Allowance and listed on the front page of U.S. Patent No. 7,498,349.

The period of adjustment under § 1.702(a) is 404 days ("A delay").

The period of adjustment under § 1.702(b) is 148 days ("B delay").

The period adjustment under § 1.704(a) is 60 days ("applicant delay").

The period of adjustment under § 1.703(f) is 492 days.

The Relevant Dates as Specified in 37 C.F.R. §§ 1.703(a)-(e) and the Adjustment Specified in 37 C.F.R. § 1.703(f)

1. § 1.703(a)

Applicants submit that the Office did correctly calculate the term adjustments to include the term adjustments that Applicants are entitled to under 37 CFR § 1.703(a)(1) as 404 days (See Exhibit A, attached hereto).

The relevant dates are shown below.

Filing Date	14-month Date	Date of 1 st Office Action	Days over 14 months (§ 1.703(a)(1))
October 6, 2005	December 6, 2006	June 27, 2007	404 days

2. § 1.703(b)

The Office failed to issue a patent within three years of the actual filing date of the above-referenced application. The period of adjustment under 37 C.F.R. § 1.702(b) begins on the day after the date that is three years from the filing date of the instant application, October 6, 2008, and ends on March 3, 2009, the day the above-identified U.S. Patent was issued.

Thus, the effective period of adjustment under 37 C.F.R. § 1.702(b) is **148 days** as shown in the table below.

Filing Date	3-year Date	Date Patent Issued	Days over 3 years through Issuance (§ 1.703(b)(1))
October 6, 2005	October 6, 2008	March 3, 2009	148 days

3. § 1.703(c)-(e)

There are no relevant dates as specified under §§ 1.703(c)-(e)

4. **Overlapping periods under § 1.703(a)-(e)**

Applicants have calculated overlapping periods in accordance with *Wyeth v. Dudas* (88 U.S.P.Q.2d 1538, D.D.C. 2008). Periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §1.54(b)(1)(B) overlap only if they occur on the same calendar day or days (*see Wyeth*).

There are no overlapping periods under § 1.703(a)-(e).

5. **§ 1.703(f)**

The period of adjustment under 37 C.F.R. § 1.702(f) is as follows:

Type "A" delay:	404 days
Type "B" delay:	148 days
"A" and "B" overlap:	0 days
Applicant delay:	60 days
<u>Adjusted</u>	<u>492 days</u>

Reduction of Period of Adjustment of Patent Term Under 37 C.F.R. §1.704

The Office did correctly calculate the period of adjustment under § 1.704(a) as 60 days as indicated by the Patent Term Adjustment History (*see Exhibit A*).

Terminal disclaimer

The instant application is not subject to a terminal disclaimer.

Statement under 37 C.F.R. § 1.705(d)

The issue fee was paid on December 15, 2008 and the U.S. Patent issued on March 3, 2009. This petition is being filed within the two-month time frame set forth under 37 CFR §1.705(d).

Pursuant to 37 CFR §1.705(d), this request for reconsideration could not have been filed prior to or with the December 15, 2008 issue fee payment since Applicants and the U.S. Patent Office are unable to calculate the amount of patent term adjustment accrued under §1.702(b) until the time of issuance of the patent. Further, knowledge of the actual date the patent issues is required to calculate any additional patent term entitled to the Applicants under §1.703(b). Thus, Applicants could not have filed the instant Request for Reconsideration prior to the issuance of the U.S. Patent.

PATENT TERM ADJUSTMENT DETERMINATION

Pursuant to *Wyeth*, Applicants are entitled to 492 days of patent term adjustment, *i.e.*, [552 days (A delay + B delay)] minus [60 days (applicant delay)].

Applicant attaches a copy of the Decision mailed on February 3, 2009 regarding the Request for Reconsideration of Patent Term Adjustment Determination filed December 15, 2008.

Based on the foregoing, Applicants respectfully request reconsideration of the patent term adjustment determination.

In accordance to the received decision dated February 3, 2009, Applicants believe that no additional fee is due since one was submitted on December 15, 2008. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 20-1430.

Respectfully submitted,



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Date Calculator Result

From 10/06/2008 to 03/03/2009 is 148 days.

New calculation